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UNITED STATES DISTRICT COURT for the DISTRICT OF NEW JERSEY

:

CHAYA GROSSBAUM and MENACHEM GROSSBAUM, her spouse, individually and as guardians ad litem of the infant ROSIE GROSSBAUM,

Plaintiffs, :

CIVIL ACTION NO. 07-CV-1359 (GEB)

vs.

GENESIS GENETICS INSTITUTE, :
LLC, of the State of Michigan,:
MARK R. HUGHES, NEW YORK :
UNIVERSITY SCHOOL OF MEDICINE :
and NEW YORK UNIVERSITY :
HOSPITALS CENTER, both :
corporations in the State of :
NEW YORK, ABC CORPS. 1-10, :
JOHN DOES 1-10, :

Defendants.

CERTIFICATION OF LEWIS STEIN, ESQ.

1. When finally received on May 8, 2009, the additional records were forwarded to Dr. Cutting. These records contained 56 color pages of graphs produced by the DNA equipment. A true

copy of 5 of these graphs received from Genesis is annexed hereto for the Court's understanding. The letters on the graphs appear to be the four component parts (proteins) of a gene sequence.

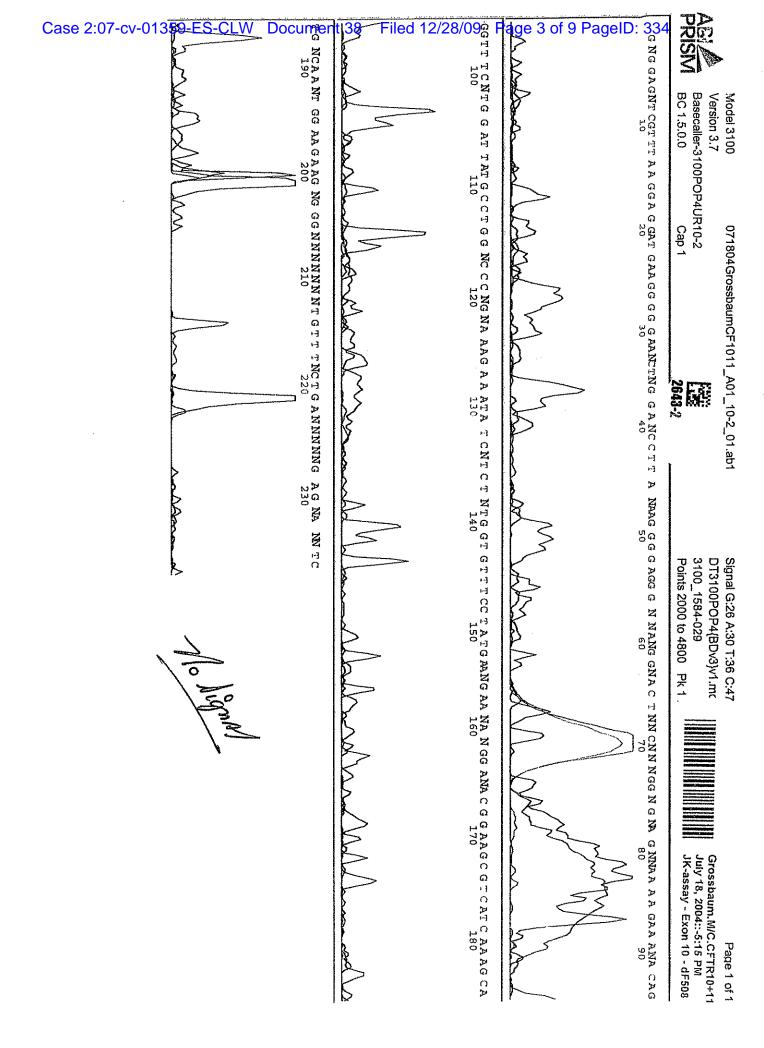
2. In addition, we annex hereto a copy of Dr. Cutting's report dated September 29, 2009 which we originally thought we would have in August of 2009 assuming he had the complete chart and all of the deposition testimony he required.

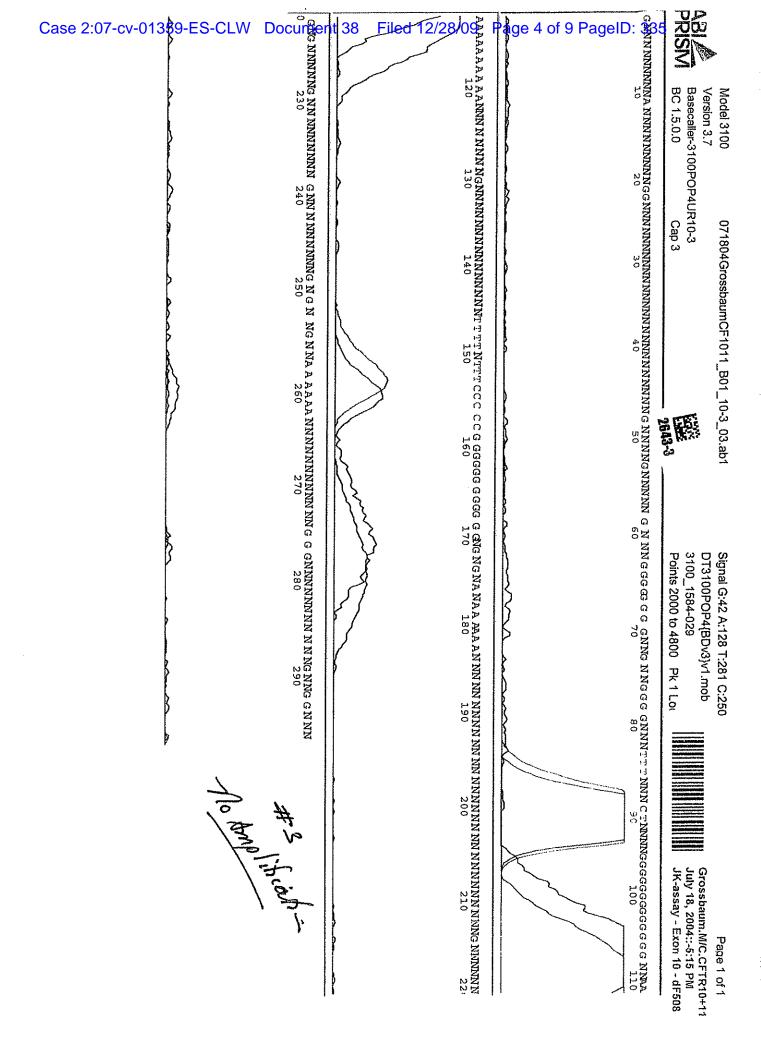
I certify that the foregoing statements made by me are true. I am aware that if any of the foregoing statements made by me are willfully false, I am subject to punishment.

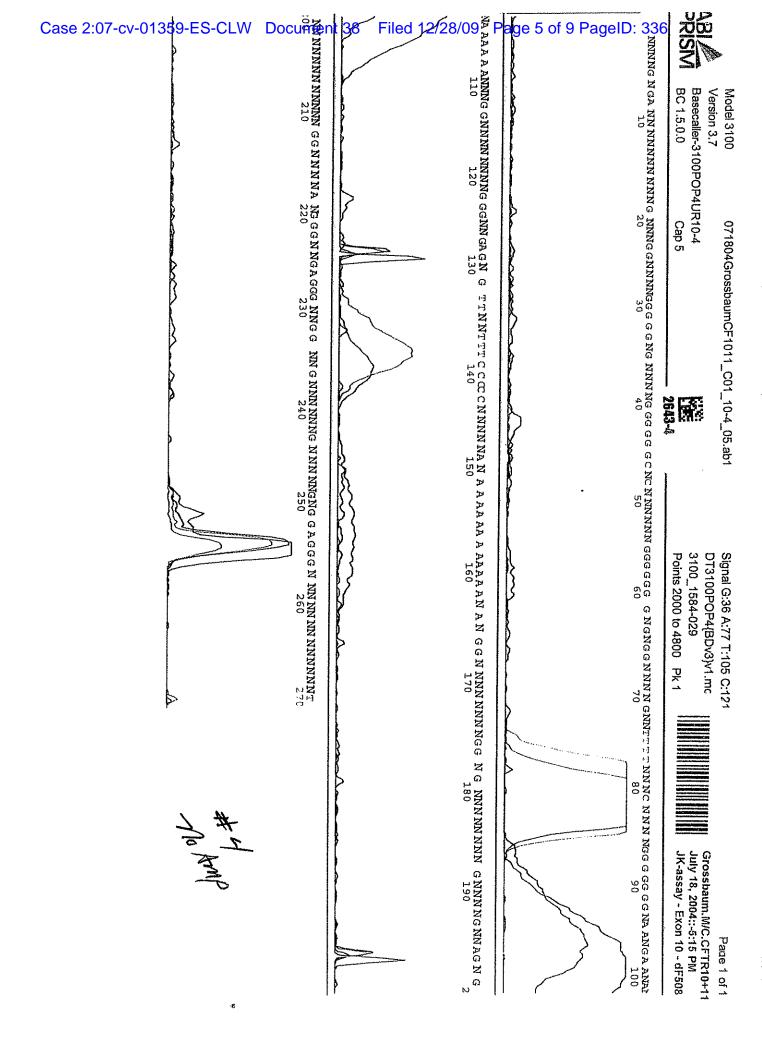
Date: December 28, 2009

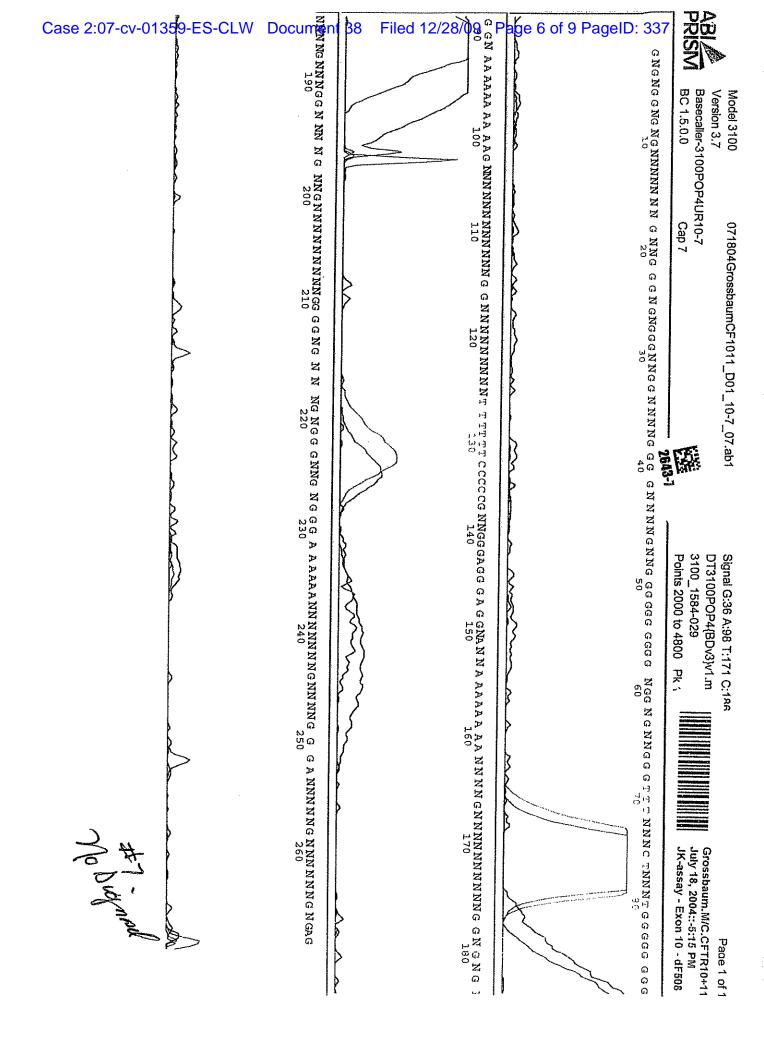
/s/ Lewis Stein
Signature of Attorney

Lewis Stein, Esq.
Printed name









JOHNS HOPKINS

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Garry R. Cutting, MD Professor, Pediatrics and Medicine Aetna/U.S. Healthcare Professor of Medical Genetics

September 29, 2009

Mr. Lewis Stein Nusbaum, Stein, Goldstein, Bronstein & Kron Counsellors at Law 20 Commerce Boulevard Succasunna, NJ 07876

RE: Grossbaum vs Genesis Genetics et al

Dear Mr. Stein,

You have asked me to provide an opinion in the above referenced case. I have reviewed records that were provided by Genesis Genetics and New York University School of Medicine, as well as depositions of Dr. Mark Hughes, Dr. Licciardi and Alexis Adler, and publications regarding multiplex marker analysis provided by Dr. Rechitsky. As I understand, the Grossbaums underwent preimplantation genetic diagnosis in which egg retrieval, *in vitro* fertilization, and embryo biopsy performed at NYU IVF Clinic. Genetic diagnosis for cystic fibrosis was performed by Genesis Genetics on samples provided by NYU. The child that was born to the Grossbaums as a result of this procedure was found to be affected with cystic fibrosis.

I have formed the opinion that there are two areas where Genesis Genetics and the NYU IVF Clinic failed to offer a reasonable level of care. The first is in the counseling of the Grossbaums regarding alternatives for embryo transfer after it was discovered that the embryos recommended for transfer by Genesis Genetics were not suitable for transfer. Allele dropout (aka ADO) is a well established source of error in preimplantation genetic diagnosis. From the deposition of Dr. Licciardi, it was apparent that he was not aware of this potential cause for error. Dr. Licciardi indicated during his deposition that he did not understand the results of the genetic testing results transmitted by Genesis Genetics. There is also no documentation of what was said during the counseling session between Dr. Licciardi and the Grossbaums regarding the risks of potential sources of error. Thus, Dr. Licciardi failed to adequately appraise the Grossbaums of the potential risks of using alternative embryos for transfer.

The second area of concern relates to the diagnostics performed by Genesis Genetics. The use of additional markers encompassing a gene such as CFTR has been shown to reduce errors due to allele dropout. Numerous manuscripts had been published and abstracts presented at national and international meetings before the date of the Grossbaums' procedure indicating the value of including genetic markers to minimize errors due to ADO. Genesis Genetics is a high profile provider of PGD services and has by their report, performed many cases of PGD for cystic fibrosis. Thus, it is reasonable to expect that Genesis Genetics would have offered multiplex DNA markers to minimize the risk of error due to ADO in the Grossbaum case. If the laboratory was unable to offer this service, then the Grossbaums should have been informed so that they would have the option to select other services that offered PGD using multiplex markers.

Please contact me should you have any further questions regarding this case.

Sincerely,

Garry R. Cutting, MD

Professor, Pediatrics and Medicine

Director, Post-Doctoral Training Program

Director, DNA Diagnostic Laboratory